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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CLOW, LORI A	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,344	PYLE ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, 4, 8, 11, and 15 , drawn to nucleic acids and compositions containing the same, classified in class 536, subclass 23.1; class 435, subclass 325. If this group is elected, please see sequence restriction requirement below.

II. Claims 2, 7, and 11, drawn to polypeptides, classified in class 530, subclass 350. If this group is elected, please see sequence restriction requirement below.

III. Claims 5, 11, and 16, drawn to antibodies, classified in class 530, subclass 387.1. If this group is elected, please see sequence restriction requirement below.

IV. Claim 6, drawn to a method for detecting the presence of pancreatic cancer by peptide expression, classified in class 435, subclass 7.1. If this group is elected, please see sequence restriction requirement below.

V. Claims 9-11, drawn to a method for stimulating and/or expanding T cells specific for a tumor protein, classified in class 435, subclass 343.2. If this group is elected, please see sequence restriction requirement below. **In addition**, if this group is elected then a specie election requirement is also required wherein the species are: Specie V(a): polypeptides; Specie V(b): polynucleotides; and Specie V(c): antigen-presenting cells.

VI. Claims 11-13 and 17, drawn to a method of treating a pancreatic cancer patient, classified in class 514, subclasses 2 and 44. If this group is elected, please see sequence restriction requirement below. **In addition**, if this group is elected then a specie election requirement is also required wherein the species are Specie

VI(a): polypeptides; Specie VI(b): polynucleotides; Specie VI(c): antibodies; Specie VI(d): T-cell populations; and Specie VI(e): antigen-presenting cells.

VII. Claim 11, drawn to a composition of antigen-presenting cells, classified in class 424, subclass 184.1. If this group is elected, please see sequence restriction requirement below. **In addition**, if this group is elected then a specie election requirement is also required wherein the species are Specie VII(a): polypeptides; Specie VII(b): polynucleotides; Specie VII(c): antibodies; Specie VII(d): T-cell populations; and Specie VII(e): antigen-presenting cells.

VIII. Claim 14, drawn to a method for detecting the presence of pancreatic cancer by nucleic acid detection, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups (I and VIII); Groups (II, IV, and VII); and Group III are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups I and VIII the critical feature is a nucleic acid; for Groups II, IV, and VII the critical feature is a polypeptide; for Group III the critical feature is an antibody. It is acknowledged that various processing steps may cause a polypeptide of the above Groups to be directed as to its synthesis by a polynucleotide of the above Groups, however, the completely separate chemical types of the inventions of the nucleic acid, polypeptide, and antibody Groups supports the undue search burden if both were examined together. Additionally, polynucleotides, polypeptides, and antibodies have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if

examined together compared to being searched separately. Also it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the three Groups of (I and VIII); (II, IV, and VII); and (III) are independent and/or distinct invention types for restriction purposes.

The inventions of Group I and Group VIII are related as product and distinct process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group I can be used in the distinct process of the invention of Group VIII. One use is directed to polypeptide expression and the other to screening via nucleic acid binding reactions. Alternatively, the nucleic acids of Group I can be used in antisense therapy which is also a clearly distinct usage of such nucleic acids.

The inventions of Group I and V are related as product and distinct process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group I can be used in the process of Group V. Alternatively the nucleic

acids of group I may be used for probe design which is a clearly distinct usage of such nucleic acids.

The inventions of Group I and VI are related as product and distinct process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids may be used in the invention process of Group VI. Alternatively, the nucleic acids may be used in antisense therapy which is a clearly distinct usage of such nucleic acids.

The inventions of Group II, IV, V, and VI are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polypeptides of Group II can be used in the distinct processes of the inventions of Groups IV, V, and VI and in therapeutic processes to replace a missing protein, or, alternatively, the activity of a protein can be utilized in an industrial process for chemical processing. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The inventions of Group III, V, and VI are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the antibodies of Group III can be used in the distinct processes of the inventions of Groups V and VI, and in Western blot analysis for protein expression studies. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The inventions of Group III and Groups (IV and VII) are related as product and distinct process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group III can be used in the distinct process of the inventions of Group (IV and VII) and in therapeutic processes to replace a missing protein, or, alternatively, the activity of a protein can be utilized in an industrial process for chemical processing.

The inventions of Groups (IV and VIII); Group V; and Group VI are independent inventions because each has different objectives, different usages, different reagents, and different methodology steps. The objectives and steps pf Groups IV and VIII are directed

to a method of cancer detection in a biological sample; while the goals of Group V are directed to a method of treating a patient; and the goals of Group VI are directed to cell culture and initiating a specific response. Therefore the methods are distinct over one another.

The inventions of Groups IV and VIII are independent inventions because they are directed to different chemical types regarding the critical limitations therein as stated above. The critical feature of Group IV is a polypeptide; while the critical feature of Group VIII is a nucleic acid. Therefore the methods are distinct over one another.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The inventions of Groups IV and V are unrelated in that the invention of Group IV is drawn to a method for detecting cancer by peptide expression and the invention of Group V is directed to a method of expanding T-cells. Both involve separate method steps and have different outcomes. The inventions are distinct for these reasons and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes is proper.

The inventions of Group IV and VII are unrelated in that the invention of Group IV is a method and the invention of Group VII is a composition. The composition of Group VII is not used in the method steps of Group IV and is thus a distinct invention.

The inventions of Group V and Groups VI and VIII are distinct in that they are different methods requiring different steps of execution and a different outcome. The

inventions are distinct for these reasons and have acquired a separate status in the art because of their recognized divergent subject matter restriction for examination purposes is proper.

The inventions of Group V and Group VII are unrelated as the method of Group V employs contact with antigen presenting cells expressing a polynucleotide and the composition of Group VII contains antigen-presenting cells expressing a polypeptide plus acceptable carriers. The antigen-presenting composition of Group VII can be used for vaccine purposes. The two are unrelated and thus restriction for examination is proper.

The inventions of Group VI and Group VII are related as product and distinct process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the composition of Group VII can be used in the distinct process of the invention of Group VI or, alternatively, the composition can be used for vaccination purposes. The inventions are distinct for these reasons and have acquired a separate status in the art because of their recognized divergent subject matter restriction for examination purposes is proper.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicant(s) must further

elect a single amino acid sequence. For an elected Group drawn to nucleic acid sequences, the Applicant(s) must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that this is a restriction requirement to a single sequence and NOT a specie election requirement.

MPEP 803.04 states:

"Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq."

It has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1(one) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

Examination will be restricted to only the elected sequence.

Species Restriction Requirement Applicable to Group V:

In addition, Group V detailed above, directed to separate chemical types, reads on patentably distinct inventions:

- Specie V(a) polypeptides
- Specie V(b) polynucleotides, and
- Specie V(c) antigen-presenting cells.

Applicant is required, in reply to this action to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted. Currently claim 9 is generic to Species V(a), V(b), and V(c). The critical limitations of each of the above chemical types are different and distinct as stated above. Examination will be restricted to only the elected specie.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and the listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103(a) of the other invention.

Species Restriction Requirement Applicable to Group VI and VII:

In addition, Group VI and VII detailed above, directed to separate chemical types, reads on patentably distinct inventions:

- Specie (a) polypeptides
- Specie (b) polynucleotides, and
- Specie (c) antibodies
- Specie (d) T-cell populations, and
- Specie (e) antigen-presenting cells.

Applicant is required, in reply to this action to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted. Currently claim 11 is generic to Species (a), (b), (c), (d), and (e). The critical limitations of each of the above chemical types are different and distinct as stated above. Examination will be restricted to only the elected specie.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and the listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D. whose telephone number is 703-306-5439. The examiner can normally be reached on Monday thru Friday, 10:00 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lori A. Clow
AU 1631

MARJORIE MORAN
PATENT EXAMINER